

AAPS/FDA WORKSHOP

AAPS/FDA Fifth Bioanalytical Workshop; Quantitative Bioanalytical Methods Validation and Implementation: The 2012 Revised FDA Guidance

BRINGING TOGETHER SMALL AND LARGE MOLECULES

Summer 2012 • Washington, D.C.

Summary/Description

The draft Food and Drug Administration (FDA) Guidance on Bioanalytical Method Validation has the potential to have a significant impact on the bioanalytical community and thereby all pharmaceutical and biotechnology companies and the contract research organizations (CROs) that support them.

Four previous conferences (1990, 2000, 2006, and 2007) between the American Association of Pharmaceutical Scientists (AAPS) and FDA were very successful. Starting in 1990, the first meeting established a dialogue between industry and agency, which was then enhanced in the subsequent meetings. The bioanalytical and scientific needs that intersected with regulatory compliance and patient safety were freely discussed and debated to produce best practices and influence the FDA in finalizing the first Guidance in 2001. The other AAPS/FDA meetings subsequent to these resulted in white papers that have served as a defacto guidance to the industry. FDA has advised the industry that it is revising the 2001 guidance to incorporate the recent advances in bioanalysis and will be publishing a draft sometime in 2012. This meeting is a proactive response to the above information.

Goals and Objectives

- To provide a forum for open discussion between industry and the agency around FDA's 2012 draft Revision to the Bioanalytical Method Validation Guidance.

continued

Detailed Program information will be available at

www.aaps.org/BMV

Call +1. 877.998.AAPS or email meetings@aaps.org for more information.